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Comparison of efficacy and safety of keto profen patch versus diclofenac patch as preemptive analgesia in patients undergoing inguinal hernia surgeries

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Abstract

Background: This study was conducted to compare the efficacy and safety of ketoprofen versus diclofenac patch for pre-emptive analgesia in patients undergoing inguinal hernia surgeries.

Method: This was a prospective, randomized, comparative clinical study conducted at MGM and MY groups of hospital, Indore, MP. 60 male patients of ASA grade 1 and 2 undergoing inguinal hernia surgeries were divided into N=30 each. Sample size calculation was based on the difference of mean of two independent samples. Trans-dermal patches of ketoprofen and diclofenac sodium were applied to the participants in both the study groups one hour prior to the induction of anesthesia.

Postoperative pain was assessed using VAS and VRS at 2,4,8,12,16 and 24 hours.

Result: Mean VAS in ketoprofen group was (2.88 ± 0.67) which was significantly low (P value less than 0.05) as compared to the diclofenac group (3.42 ± 0.17) . Likewise, VRS mean in ketoprofen group (1.60 ± 0.34) was low as compared to diclofenac group (1.81 ± 0.23) suggesting better efficacy of ketoprofen patch over diclofenac patch. Data were analysed using unpaired students T test.

Conclusion: In our study we found ketoprofen patch as better analgesic then diclofenac patch for post-operative hernia surgeries pain. Also the transdermal route is very comfortable for the patient compared to oral, intramuscular, intravenous route for pain alleviation.

Keywords: Diclofenac sodium, ketoprofen, pre-emptive analgesia, transdermal patch

Introduction

Pain is the most feared component of any surgical procedure and of postoperative period [1-2]. Adequate analgesia is the basic and most required need for patient's comfort. Pain response due to skin incision and tissue injury is influenced by many factors like personality, belief, gender, surgical approach, age, fear, anxiety, pre-existing pain syndrome etc. [3] Poorly treated postoperative pain could lead to complications like anxiety, depression, tachycardia, hypertension, myocardial infarction, delayed mobility and recovery, increased hospital stay etc. Pain occur due to tissue injury that in turns leads to modification of nervous system in two ways:

- a) **Peripheral sensitization:** that is reduced threshold of efferent nociceptives.
- b) **Central sensitization:** increase spinal nervous excitability leading to neuroplasticity.

These conditions lead to hypersensitivity to pain which will be felt with increased intensity in postoperative period. This is why pre-emptive analgesia is required to reduce these complications of pain [4-5].

Inguinal hernia [6-7] is the most common type of all the abdominal wall hernias with former representing 75% of all Surgeries for inguinal hernia have promising results but postoperative pain if ill-treated can lead to complications and thus delay recovery.

Pain is usually managed with systemic analgesics belonging to different classes like NSAIDS, opioids, glucocorticoids, local anesthetics, α -2 agonists, ketamine, gabapentinoids etc. [8]. Commonly used routes are oral and parental but transdermal route is a recent innovative way of providing analgesia with ease for longer period over 24 hours, consistent plasma drug level because of sustained drug delivery system, less side effects and irritation and better patient's compliance [9-10].

This study is conducted to compare the efficacy of diclofenac and ketoprofen transdermal patch for postoperative pain relief via transdermal route for inguinal hernia surgeries.

Aims and objectives**Primary objectives**

1. To compare the quality and duration of analgesia after transdermal diclofenac sodium and ketoprofen patch.
2. To compare the timing of rescue analgesia after transdermal diclofenac sodium and ketoprofen patch.

Secondary objectives

1. To compare the advantages and disadvantages of both the drugs via transdermal route.
2. To see untoward effects if any.

Material and method

This study was conducted over a period of one year at Department of Anesthesiology at MGM Medical College and M.Y. groups of hospital, Indore.

Sample size: 60 patients of ASA grade 1 and 2 were divided into two groups (K-ketoprofen and D- diclofenac sodium, of 30 patients each) scheduled for elective inguinal hernioplasty under subarachnoid block. Sample size was calculated on the basis of difference of mean of two independent samples.

Inclusion criteria

- ASA physical status 1 and 2
- age from 18 to 50 years
- gender male

Exclusion criteria

- Patient refusal
- Skin diseases
- Patient hypersensitivity reaction to the study drugs
- Bleeding disorders, gastrointestinal disorders like ulcer, perforation
- Patients with severe hepatic and renal disorders
- Contraindication to subarachnoid block
- Patient on antipsychotics

Randomization: Patients were randomly allocated by computer generated random tables to one of the two groups comprising 30 patients each.

Procedure: After obtaining written informed consent and confirming NPO status, baseline vitals were recorded and intravenous fluid (Ringer lactate @15ml/kg/hour) was started. Routine monitors like Spo₂, heart rate, NIBP, respiratory rate and ECG were connected. Subarachnoid block was given in sitting position at L3-L4 intervertebral space using 25 Gauge Quincke's needle under all aseptic precautions and 3ml of 0.5% hyperbaric bupivacaine given.

Sensory blockade up to T10 level was obtained and confirmed. Out of two study groups, in group D patients were applied with transdermal diclofenac patch containing 100 mg of diclofenac diethylamine one hour prior to induction of anesthesia. While in Group K, transdermal ketoprofen patch containing 20 mg of ketoprofen was applied one hour prior to anesthesia induction.

Statistical analysis: Data was initially entered into the microsoft excel sheet from the customized performa for analysis. Mini Tab version 17.0 was used for calculating the P values. A P value of less than 0.05 was taken as statistically significant. Unpaired T test was used for comparing means between two groups. Descriptive statistics was presented in the form of numbers and percentages and the final data was presented in the form of tables and graphs.

Assessment of postoperative pain and management: Pain was assessed postoperatively at 2, 4, 6, 8, 12, 16 and 24 hours by using visual analogue scale (VAS score) and verbal rating scale (VRS Score). At any time during the study if the VAS was more than 5 or VRS more than 1 then an injection of inj. Tramadol 2 mg/kg was administered as rescue analgesia and the study ended. Time of rescue analgesia was noted for all the patients.

Observations and results

Demographic data are comparable in both the study groups without any statistical significance ($p > 0.05$). VAS score in group K was (2.88+0.6) while in group D, it was (3.42+0.10) showing significantly better pain control in group K compared to group D. VRS score in group K was (1.60+0.34) and in group D was (1.81+0.23) showing significantly better VRS in group K compared to group D ($p < 0.05$).

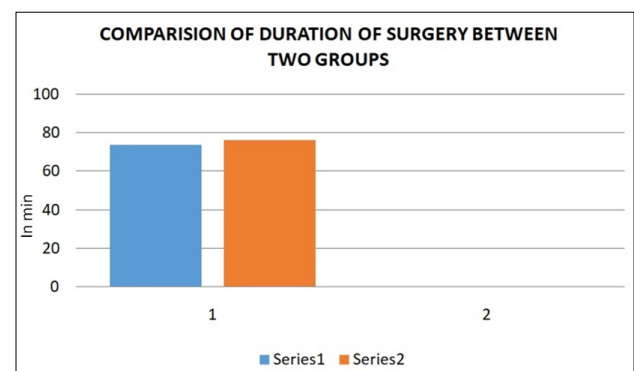
Comparison of age between two study group

Fig 1: Comparison of duration of surgery between two group

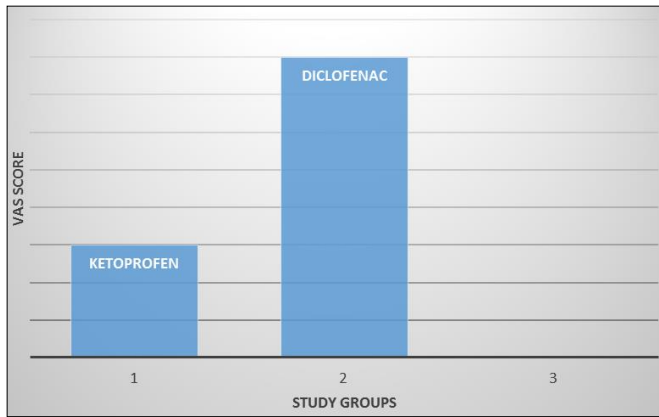


Fig 2: VAS score

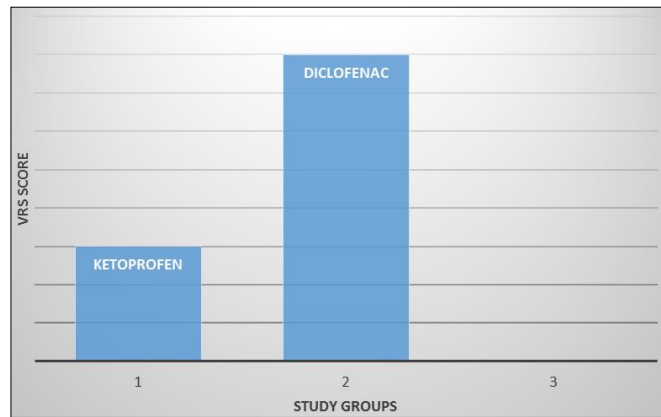


Fig 3: VRS Score

Discussion

Perioperative pain management is of at most importance for successful surgical outcome. Pre-emptive analgesia that is analgesia given before the initiation of the pain response reduces postoperative pain as well as overall analgesic requirements. Also it is associated with lesser side effects like nausea, vomiting, anxiety, hypertension etc. and aids in smooth and speedy recovery which in turn reduces overall hospital stay^[11].

Pain control is done with various routes, most common of those are oral and parenteral like intramuscular, intravenous etc. Transdermal route is recent in course with an edge over other parental routes like sustained drug delivery maintaining constant plasma level of drug, single painless application of patch over 24 hours, increased bioavailability, self-administration, easy termination, better patient compliance and also less attention seeking from medical staff.

In present study, we have compared two drugs belonging to NSAIDS-diclofenac and ketoprofen via transdermal route for postoperative pain relief in patients undergoing inguinal hernioplasty.

Transdermal route is also better than oral route for postoperative pain management as it avoids first pass metabolism and gastrointestinal upset and better than intramuscular, intravenous route because of pain and irritation associated with later routes. NSAIDS inhibit cyclo-oxygenase 1 & 2, key enzymes in prostaglandin biosynthesis. In present study, ketoprofen and diclofenac transdermal patches were used for pain relief during inguinal hernioplasty.

In our study, patient in two groups were comparable in the demographic data like age, weight, duration of surgery with P value greater than 0.05 that is statistically insignificant.

Duration of analgesia was measured by a VAS score that is (2.88 + 0.67) in ketoprofen group and (3.42 + 0.10) in diclofenac group showing significantly better pain relief in ketoprofen group.

Kawai *et al.*^[12] conducted study and found ketoprofen patch to be better than placebo for relieving pain in patients of rheumatoid arthritis.

Reetu *et al.*^[13] conducted study in orthopedic surgery. They found results in concordance with our study that is ketoprofen patch is more efficacious than diclofenac patch for pain relief.

Maziers *et al.*^[14] compared ketoprofen and placebo patch for ankle sprain and found ketoprofen to be more effective.

Sarzi-puttini *et al.*^[15] conducted study and observed result

similar to our study that is ketoprofen is better than diclofenac and ibuprofen as analgesic.

VRS compared after 24 hours in our study showed significantly low mean VRS score in ketoprofen group (1.60 + 0.34) as compared to diclofenac group (1.81 + 0.23) showing ketoprofen to be better analgesic than diclofenac.

Timing of rescue analgesia and complications were statistically insignificant in our study. Patch related local side effects were nil.

Safety of NSAIDS transdermal patches was studied by Mason *et al.*^[16] and Predal *et al.*^[17] and found to be safe and well tolerated.

Rationale of study: This study was conducted to assess the viability and efficacy of transdermal patches as pre-emptive analgesia to decrease postoperative pain and hence to decrease the hospital burden in terms of stay and cost.

Conclusion: it is concluded from our study that transdermal 20 mg ketoprofen patch is better analgesic than 100 mg diclofenac via transdermal route for pre-emptive analgesia in patients undergoing inguinal hernioplasty.

Limitation of study: We did not consider the stress response in either groups for which the measurement of serum cortisol would have been required. Also we did not include a placebo group as it would have been unethical.

Conflict of interest none.

Source of funding none.

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